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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KAPUST, RACHEL B	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,547	CURTIS, RORY A.J.	
	Examiner	Art Unit	
	Rachel B. Kapust	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *8-11 and 13-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,12 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I (encompassing original claims 1-7 and 12 and new claims 23-25) is acknowledged.

The restriction requirement is still deemed proper and is therefore made FINAL. Claims 8-11 and 13-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-7, 12, and 23-25 are under consideration.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specification

The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable codes (see, for example, p. 6, 8, 9, 25, and 26). Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01.

The use of the trademarks BIACORE™ (p. 55), SEPHAROSE™ (p. 55), CREMOPHOR™ EL (p. 76), SUPERSCRIPT™ (p. 98), TAQMAN™ (p. 98), and ABI PRISM™ (p. 98) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5, 6, 23, and 24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 5, 6, 23, and 24 are drawn to host cells and mammalian host cells comprising a nucleotide sequence encoding a 25466 protein. The claims read on cloned humans which are non-statutory subject matter. The rejection may be obviated

by amending the claims to read "an isolated non-human host cell" so long as there is support for the amendment in the specification.

Claims 1-7, 12, and 23-25 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 1-7, 12, and 23-25 are directed to isolated nucleic acid molecules comprising SEQ ID NO: 1 or 3 or nucleic acid molecules encoding a polypeptide comprising SEQ ID NO: 2. The specification asserts that the polypeptide encoded by SEQ ID NO: 2 (protein 25466) is a member of the monocarboxylate transporter (MCT) family (p. 3). The claimed nucleic acid molecules are not supported by either a specific and substantial asserted utility or a well-established utility.

A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" use for the claimed invention. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966):

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

Uses such as screening assays (p. 52), making antibodies (p. 42), and generating antisense nucleic acid to inhibit expression of the 25466 protein (p. 33) are useful only in research to determine the function of the encoded protein itself. There is no "specific benefit in currently available form" to be derived from such studies. Tissue-specific expression such as that found on p. 13 is not specific to the claimed polynucleotide. It does not depend on any characteristics of the nucleic acid molecule itself. Further, while applicants list a number of diseases such as various neurological disorders, salivary gland disorders, and cellular proliferative and/or differentiative disorders (p. 14-16), the specification does not disclose any diseases or conditions known to be associated with the encoded protein. All Applicant has shown is varying expression of the claimed nucleic acid molecules in a number of normal cell

lines and cancer cell lines. Merely listing a number of possibilities is not sufficient to identify or confirm a "real world" context of use; clearly further research would be required to identify a disease in which the encoded protein is involved. Thus, significant further research is required to identify a disease for which it could be used, or a disease for which its presence would be diagnostic. See *Brenner v. Manson*, noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." A patent is therefore not a license to experiment. Further research would be required to determine how and if protein 25466 is involved in the aforementioned diseases.

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and credible utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. The specification fails to assert any activity for the encoded polypeptide other than those generally recognized to be attributes of polypeptides in the MCT family. Identifying a nucleic acid molecule as encoding a polypeptide of this family does not endow the nucleic acid molecule with a specific and substantial utility. MCTs transport lactic acid, pyruvate, acetoacetate, β-hydroxybutyrate, and acetate across plasma membranes (Price *et al.* (1998), *Biochem. J.* 329: 321-328). Price *et al.* teach each member of the MCT family have slightly different properties related to the metabolic requirements of the tissues in which they are found (p. 321, column 1). Price *et al.* further teach that depending on the relatedness of MCTs, the less related members might be involved in the transport of unrelated molecules (p. 325). Thus, simply knowing that a protein is a member of the MCT family does not impart a function on the polypeptide. One of skill in the art would not know what molecules that MCT-like protein would transport. Moreover, even if one of skill in the art knew what molecules the MCT-like protein transported, one would still not know what biophysical effects the MCT-like protein would have on the cellular environment. The biophysical and pharmacological characteristics of a MCT-like protein could not be discerned by simply identifying it as a member of the MCT family. There is therefore no well-established utility for members of this family; utility is specific to the individual protein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 12, and 23-25 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1, 3-7, 12, 23, and 24 are rejected under 35 U.S.C. 112, first paragraph because the specification, were it enabling for a nucleic acid molecule comprising SEQ ID NO: 1 or 3 or a nucleic acid molecule encoding SEQ ID NO: 2, would not reasonably provide enablement for polynucleotides that encode at least 120 contiguous amino acids of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the polypeptide that are tolerant to change and the nature and extent of changes that can be made in these positions. For instance, SEQ ID NO: 2 is 510 amino acids in length, and SEQ ID NO: 3, which encodes SEQ ID NO: 2, is 1533 nucleotides in length. The claims are drawn to nucleic acid molecules encoding at least 120 contiguous amino acids of SEQ ID NO: 2. These sequences could be extremely different from that of SEQ ID NO: 3. Moreover, even though the claims encompass hundreds of thousands of sequences, there are no functional limitations for the sequences in the claims. The encoded polypeptides could have structures that are very different from that of SEQ ID NO: 2, and the functions could be very different from that of a polypeptide comprising SEQ ID NO: 2. The specification provides no guidance as to which (if any) of the nucleotides can be changed or deleted to yield a functional equivalent of the polypeptide comprising SEQ ID NO: 2. More importantly, because there is no specific activity

disclosed for the polypeptide comprising SEQ ID NO: 2, and there is no functional limitation in the claim, there would be no means for predicting or identifying other polypeptides that would have a similar activity.

The problem of predicting polypeptide structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the polypeptide is extremely complex. While it is known that many amino acid substitutions are generally possible in any given polypeptide, the positions within the polypeptide's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the polypeptide's structure/function relationship, such as various sites or regions directly involved in binding, activity, and in providing the correct three-dimensional spatial orientation of binding and active sites. Particular regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions.

Due to the large quantity of experimentation necessary to generate the infinite number of variants recited in the claims and screen the same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on polypeptide structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

In addition, claims 1, 3-7, 12, 23, and 24 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to a genus, *i.e.* variants of nucleic acid molecules encoding SEQ ID NO: 2. The genus includes fragments of a nucleic acid molecule encoding SEQ ID NO: 2 and nucleic acid molecules encoding allelic variants of SEQ ID NO: 2. Because the claims have no functional limitations, the claims are drawn to a genus of

nucleic acid molecules that is defined by sequence identity. Applicant has disclosed one species, nucleic acid molecules consisting of SEQ ID NO: 1 or 3, but have not disclosed sufficient species for the broad genus which includes fragments of a nucleic acid molecule encoding SEQ ID NO: 2 and nucleic acid molecules encoding allelic variants of SEQ ID NO: 2.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. The instant disclosure of two species of nucleic acid molecules does not adequately describe the scope of the claimed genus, which encompasses hundreds of thousands of different nucleic acid molecules encoding polypeptides with varying structures and functions. The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of nucleic acid molecules. Structural features that could distinguish the compounds in the genus from other nucleic acid molecules encoding monocarboxylate transporter polypeptides are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teaching sufficient to enable one of skill to isolate and identify the nucleic acid molecules encompassed: there is no guidance in the art as to what the defining characteristics of a 25466 polypeptide might be. Thus, no identifying characteristics or properties of the instant nucleic acid molecules are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

In this case, Applicant provides no information as to the structures of the allelic variants or the fragments of nucleic acid molecules. The only information provided is that they are allelic variants of a 25466 protein or they encodes at least 120 contiguous amino acids of SEQ ID NO: 2. Applicant is claiming a species which has not been sufficiently described, *i.e.* Applicant is claiming sequences that have not yet been identified. Only once the nucleic acid molecules have been sequenced and their functions have been determined can a person of skill in the art determine that the nucleic acid molecules are allelic variants of a 25466 protein. Accordingly, one of skill in the art would doubt that Applicant had possession of the claimed species at the time the application was filed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic acid molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, the disclosure of SEQ ID NOS: 1 and 3 is insufficient to describe the genus. Therefore, only isolated nucleic acid molecules comprising SEQ ID NO: 1 or 3 or encoding a polypeptide comprising SEQ ID NO: 2 but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, 3-7, 12, and 23-24 are drawn to nucleic acid molecules that hybridize to SEQ ID NO: 1 or 3 under stringent conditions. The term "stringent conditions" is a relative term which renders the claims indefinite. The term is not defined by the claim, and whereas the specification provides examples of stringent conditions (p. 22), the specification neither provides a definition of stringent conditions nor a standard for ascertaining the requisite degree, and one skilled in the art would not be reasonably apprised of the scope of the invention. It is unclear what amount hybridizing would occur under "stringent" conditions. One skilled in the art would not know what the metes and bounds of stringent conditions are.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 12, and 23-25 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by WO 01/60860 (Schlegel *et al.*). Claims 1-7 and 25 are drawn to isolated nucleic acid molecules comprising either SEQ ID NO: 1 or 3 or nucleic acid molecules encoding a polypeptide comprising SEQ ID NO: 2 and fragments thereof wherein the fragments encode at least 120 contiguous amino acids of SEQ ID NO: 2, vectors comprising the isolated nucleic molecules, and host cells comprising the nucleic acid molecules. Claims 12 and 23-24 are drawn to host cells expressing SEQ ID NO: 1 or 3 or a nucleic acid molecule encoding a polypeptide comprising SEQ ID NO: 2 and methods for producing polypeptides comprising SEQ ID NO: 2.

Schlegel *et al.* teach a nucleic acid sequence (ABV26931 standard) which is 100% identical to SEQ ID NO: 3 (see attached alignment). Schlegel et al teach vectors comprising the nucleic acid sequence, host cells comprising the vectors, recombinant expression of the nucleic acid sequence to produce a polypeptide (p. 55, line 17 through p. 60, line 20). Thus, claims 1-7, 12, and 23-25 are anticipated by Schlegel *et al.*

Claims 1, 3-7, 12, and 23-24 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by US 2003/0219745 (Tang *et al.*). Claims 1, 3-7, 12, and 23-24 are as described above. Tang *et al.* teach SEQ ID NO: 324, which encodes a polypeptide that is 99.4% identical to SEQ ID NO: 2 (see attached alignment). SEQ ID NO: 324 is also 99.8% identical to SEQ ID NO: 3 (see attached alignment), and the encoded polypeptide comprises at least 120 contiguous amino acids of SEQ ID NO: 2. Tang *et al.* teach vectors comprising SEQ ID NO: 324 (see paragraphs 0086-0089) host cells comprising SEQ ID NO: 324 (see p. 11), and methods of producing recombinant polypeptides (see paragraphs 0118-0119). Thus, claims 1, 3-7, 12, and 23-24 are anticipated by Tang *et al.*

Claims 1, 3-7, 12, and 23-24 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by US 2004/0024183 (Lee *et al.*) Claims 1, 3-7, 12, and 23-24 are as described above. Lee *et al.* teach SEQ ID NO: 46 which is 90.3% identical to SEQ ID NO: 3 (see attached alignment). SEQ ID NO: 46 encodes a polypeptide that is 90.2% identical to SEQ ID NO: 2 (see attached alignment), and the encoded polypeptide comprises at least 120 contiguous amino acids of SEQ ID NO: 2. Lee *et al.* teach vectors comprising SEQ ID NO: 46 (see paragraph 0140), host cells (see paragraphs 0185-0188), and methods of producing recombinant polypeptides (see paragraph 0182). Thus, claims 1, 3-7, 12, and 23-24 are anticipated by Tang *et al.*

Conclusion

NO CLAIMS ARE ALLOWED.

The following articles, patents, and published patent applications were found by the Examiner during the art search while not relied upon are considered pertinent to the instant application:

Zhao *et al.* (2001), *Diabetes* 50: 361-366

Galic *et al.* (2003), *Biochem. J.* 376: 413-422

Enerson *et al.* (2003), *J. Pharm. Sci.* 92(8): 1531-1544

Juel *et al.* (1999), *J. Physiol.* 517(3): 633-642

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RBK
3/8/04

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